

Notices of Final Rulemaking

NOTICES OF FINAL RULEMAKING

The Administrative Procedure Act requires the publication of the final rules of the state's agencies. Final rules are those which have appeared in the *Register* first as proposed rules and have been through the formal rulemaking process including approval by the Governor's Regulatory Review Council or the Attorney General. The Secretary of State shall publish the notice along with the Preamble and the full text in the next available issue of the *Register* after the final rules have been submitted for filing and publication.

NOTICE OF FINAL RULEMAKING

TITLE 9. HEALTH SERVICES

CHAPTER 13. DEPARTMENT OF HEALTH SERVICES HEALTH PROGRAMS SERVICES

Editor's Note: The following Notice of Final Rulemaking was reviewed per Executive Order 2012-03 as issued by Governor Brewer. (See the text of the executive order on page 978.) The Governor's Office authorized the notice to proceed through the rulemaking process on November 28, 2012.

[R14-54]

PREAMBLE

- | <u>1. Article, Part, or Section Affected (as applicable)</u> | <u>Rulemaking Action</u> |
|--|--------------------------|
| R9-13-201 | Amend |
| R9-13-202 | Amend |
| R9-13-203 | Amend |
| R9-13-204 | Amend |
| R9-13-205 | Amend |
| R9-13-206 | Amend |
| R9-13-207 | Amend |
| R9-13-208 | Amend |
- 2. Citations to the agency's statutory rulemaking authority to include the authorizing statute (general) and the implementing statute (specific):**
Authorizing statutes: A.R.S. §§ 36-132(A)(1), 36-136(A)(7), and 36-136(F)
Implementing statutes: A.R.S. § 36-694, as amended by Laws 2012, Ch. 299, § 2
- 3. The effective date of the rules:**
April 1, 2014
The Department requests an immediate effective date for these rules under A.R.S. § 41-1032 (A)(1) and (4). These rules will enable the Department to collect increased fees to run the Newborn Screening Program (NBS), which will enable the Department to continue the testing of newborns for 28 disorders. Newborns with abnormal screening test results for these 28 disorders or for hearing loss will continue to receive follow-up services to help assure they receive diagnostic testing and any treatment they may need. Newborns and infants with one of the disorders detected through screening or with a hearing loss, their parents, and society in general will benefit from an immediate effective date for the rules. The increased fees will allow the Department to provide more accurate testing with fewer false positive results, more thorough follow-up on abnormal results, more extensive provider education to reduce time from specimen collection to submission and testing, and more comprehensive quality assurance activities. No penalties are assessed for a violation of the rules.
- 4. Citations to all related notices published in the *Register* as specified in R1-1-409(A) that pertain to the record of the final rulemaking package:**
Notice of Rulemaking Docket Opening: 19 A.A.R. 154, February 1, 2013
Notice of Proposed Rulemaking: 20 A.A.R. 64, January 10, 2014
- 5. The agency's contact person who can answer questions about the rulemaking:**
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6. An agency's justification and reason why a rule should be made, amended, repealed or renumbered, to include an explanation about the rulemaking:

Arizona Revised Statutes (A.R.S.) § 36-694 contains requirements for ordering tests for certain congenital disorders and for reporting congenital disorder test results and hearing test results to the Department, and establishes a newborn screening program, a central database for information about newborns and infants who are tested for hearing loss or congenital disorders, an educational program and follow-up services, and a newborn screening program committee. Current rules in Arizona Administrative Code (A.A.C.) Title 9, Chapter 13, Article 2, specify the congenital disorders being tested for, the information required to be submitted when a bloodspot specimen is collected from a newborn or infant, the person responsible for collecting the specimen, when the specimen should be collected, reporting requirements for a bloodspot test, reporting requirements for hearing tests, and fees. Laws 2012, Ch. 299, § 2, removed the statutory fee cap for a second specimen for newborn screening from A.R.S. § 36-694 and allows the Department to establish the fee for a second specimen through rulemaking. The Department is amending the newborn screening rules in 9 A.A.C. 13, Article 2, to increase the fee for a second specimen to cover the costs associated with testing and follow-up for the disorders specified in the rules and billing for these activities. Laws 2008, Ch. 225, § 1, made the Arizona State Laboratory the "only testing facility for the program," removing the requirement for solicitation for testing by a contracted entity. In this rulemaking, the Department is also amending the rules to comply with Laws 2008, Ch. 225, and making other changes, as identified in the previous five-year-review report, that clarify requirements in the rules to reduce the burden on stakeholders. The Department received an exception from the Governor's rulemaking moratorium, established by Executive Order 2012-03, for this rulemaking. The amended rules conform to rulemaking format and style requirements of the Office of the Secretary of State.

7. A reference to any study relevant to the rule that the agency reviewed and proposes either to rely on or not to rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

The Department reviewed and relied on an article in the Milwaukee Journal Sentinel (<http://www.jsonline.com/watchdog/Deadly-Delays-Watchdog-Report-newborn-screening-program-231927171.html>), which identified and described problems with Arizona's newborn screening. These included hospitals not sending specimen collection kits to the Department in a timely fashion, which had not been addressed due to lack of funding for adequate staffing. Although not a study, the Department also reviewed and relied on information described in the January 30, 2004 edition of the *Morbidity and Mortality Weekly Report* (MMWR), a publication of the Centers for Disease Control and Prevention, pages 57-59, which provided the economic costs associated with mental retardation, such as may occur if a baby with Congenital Hypothyroidism or Phenylketonuria is not diagnosed and treated in a timely manner, and with hearing loss, if not diagnosed early and intervention strategies implemented.

8. A showing of good cause why the rulemaking is necessary to promote a statewide interest if the rulemaking will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

9. The summary of the economic, small business, and consumer impact:

Annual costs/revenues changes are designated as minimal when \$1,500 or less, moderate when between \$1,500 and \$15,000, and substantial when \$15,000 or greater in additional costs or revenues. A cost is listed as significant when meaningful or important, but not readily subject to quantification.

The Department will experience a significant benefit from specifying that the Arizona State Laboratory is the screening laboratory for bloodspot specimens and from clarifying other requirements in the rules. The Department will receive a substantial benefit from the fee increase for a second specimen. During FY 2013, the Department received 83,888 first specimens and 75,444 second specimens for bloodspot testing. Currently, the fee for a first specimen is \$30 and for a second specimen is \$40, which had been capped in statute. The newborn screening bloodspot testing produced 2,018 abnormal test results. The Department received 85,869 hearing test results, of which 2,940 indicated

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an abnormal result. All babies with an abnormal test result received follow-up, which resulted in the diagnosis of 116 babies with one of the 28 congenital disorders and 152 babies with a diagnosed hearing loss. In FY 2013, the Department billed \$5,538,700 for newborn screening and collected \$4,613,595 in fees to support NBS. This amount is insufficient to provide newborn screening program activities in an effective manner, despite cost-cutting measures undertaken by the Department to help off-set the deficit. To adequately provide bloodspot testing for 28 congenital disorders and follow-up for newborns and infants who had an abnormal screening test result for one of the 28 congenital disorders or hearing loss, as well as to bill for specimens submitted, the Department requires approximately \$7,300,000. The Department anticipates that the fee increase of \$25 (from \$40 to \$65) for second specimens will provide sufficient funding to cover the deficit of approximately \$1,796,000. The Department plans to use these funds to address critical issues that have arisen as a result of the cost-cutting measures. These include hiring four new staff to fill existing vacant positions of staff lost through attrition and not replaced (Public Health Scientist, Blood-spot Follow-up Specialist, Hearing Follow-up Specialist, and Educator/Epidemiologist); replacing aging instruments to enable the Department to provide more reliable testing for metabolic diseases, cystic fibrosis, and hemoglobin diseases; and consolidating the four database management systems in current use. The Department may also receive a significant benefit from collecting a mother's date of birth as part of all hearing test results.

AHCCCS is expected to incur a substantial cost due to the fee increase for second specimens. According to CY 2012 birth data from the Department's *Health Status and Vital Statistics* publication, AHCCCS covers approximately 53.1% of births. According to figures received from AHCCCS, the cost impact from the fee increase for second specimens will range from \$838,000 to \$1.8 million. Based on the total amount billed to AHCCCS in FY 2013, the Department billed for \$1,333,440 for 33,336 second specimens from babies covered under AHCCCS and collected \$1,140,024. With a \$25 increase in the fee for a second specimen and a similar number of specimens, the Department anticipates that AHCCCS may incur an additional \$833,400 in costs as a result of the fee increase. The Department anticipates that AHCCCS may receive a significant benefit from the rulemaking. Any reduction in NBS would impose an additional burden on AHCCCS through missed babies with a congenital disorder or hearing loss for which AHCCCS would bear costs for diagnostic testing once symptoms develop and on-going medical expenses to treat the symptoms of the congenital disorder. The increase in the fee for a second specimen will allow the Department to make changes to bloodspot testing that will minimize the number of false positives, test results that are abnormal and indicate the need for further testing for a baby who is found through the further testing to not have a congenital disorder. Reducing false positives will reduce AHCCCS's costs associated with unnecessary and expensive diagnostic testing and family provider visits. The amount of the benefit would depend on how many babies covered by AHCCCS were diagnosed with a congenital disorder or had a false positive result.

Third-party payors, including private insurance plans, military health care facilities, Indian Health Service, and tribal health care facilities, paid for approximately 43.3% of births in Arizona in 2012, based on data from the Department's *Health Status and Vital Statistics* publication. Third-party payors as a whole are expected to incur a substantial cost due to the fee increase for second specimens; the cost incurred by a specific third-party payor would vary depending on the number of covered births. During FY 2013, the Department billed more than thirty third-party payors \$979,898 for 24,516 second specimens. The largest third-party payor was Aetna, to which 5,255 second specimens were billed. The Department collected approximately \$397,739 from third-party payors as a result of this billing. In upcoming years, the Department anticipates that third-party payors will be billed approximately \$625,000 more for 25,000 second specimens as a result of the fee increase, and that the Department will collect approximately \$550,000. Therefore, the Department anticipates that the additional annual costs to third-party payors as a whole for increased newborn screening fees may be substantial, and the cost to an individual third-party payor to range from minimal to substantial, depending on the number of covered babies. The Department estimates that the additional costs to third-party payors from the increased newborn screening fees will essentially be offset from increased insurance premiums. As with AHCCCS, the Department anticipates that third-party payors may receive a significant benefit from the changes to address critical issues, made possible by the fee increase.

Physicians and outpatient treatment centers order the collection of the majority of second specimens. A physician or an outpatient treatment center submitting a second specimen may be billed for the second specimen if the physician or outpatient treatment center does not provide the information specified in R9-13-203(C)(2)(b) or (c). Only a small percentage of second specimens submitted by physicians and outpatient treatment centers are billed to these physicians or outpatient treatment centers. During FY 2013, the Department billed physicians and outpatient treatment centers \$73,470 for 1,840 second specimens (approximately 2.4% of second specimens) and collected \$57,130. The Department estimates that physicians and outpatient treatment centers may be billed an extra \$45,000 due to the fee increase, and that the Department will collect approximately \$39,100. While, the Department anticipates that physicians and outpatient treatment centers, as a whole, may incur a substantial increase in costs due to the fee increase, based on the number of specimens billed to the largest such submitter, an individual physician or outpatient treatment center may incur at most moderate costs due to the fee increase for second specimens, depending on the number of second specimens for which they are billed. Clarification of when a second specimen is collected may provide a significant benefit to a physician or outpatient treatment center.

Hospitals collect less than a third of second specimens and include information for billing on some of the specimens submitted. During FY 2013, hospitals were billed \$517,780 for 12,961 second specimens. The Department collected \$496,630 as a result of the billing. The Department estimates that hospitals may be billed an extra \$324,025 as a result of the fee increase. Since the Department billed 1,886 second specimens to the largest hospital submitter during

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FY 2013, the Department anticipates that a hospital may incur minimal-to-substantial costs due to the fee increase for second specimens, depending on the number of second specimens submitted for which the hospital is billed. Changes made to requirements for information on the specimen collection kit and reductions in false positive results may also provide a significant benefit to a hospital.

Midwives as a whole submit less than 300 second specimens per year, many of which contain the information specified in R9-13-203(C)(2)(b) or (c). The additional costs incurred by a midwife for submitting a second specimen will vary with the number of the second specimens for which the midwife does not provide the information specified in R9-13-203(C)(2)(b) or (c). During FY 2013, the Department billed midwives \$6,000 for 150 second specimens, most of which may be reimbursed by parents. The Department anticipates that midwives as a whole may be billed an extra \$3,750 due to the fee increase, and that the Department may collect \$3,500 as a result of the billing. The Department billed 57 second specimens to the largest midwife submitter during FY 2013. If a similar number of second specimens is submitted by individual midwives in upcoming years, the increase in cost for an individual midwife may be none-to-minimal, depending on the number of second specimens submitted without the information in R9-13-203(C)(2)(b) or (c). As with hospitals, physicians, and outpatient treatment centers, midwives may receive a significant benefit from changes made by this rulemaking related to the information required to be submitted and the reduced number of false positive test results, with the extent of the benefit depending on the number of specimens submitted and the number of babies with a false positive result who are under the care of a midwife.

Audiologists, hospitals, and others performing hearing tests report the results of both initial hearing screening tests and subsequent hearing screening or diagnostic tests. The Department anticipates that clarifying reporting requirements and removing some redundant requirements may provide a significant benefit to and are expected to impose at most a minimal burden on audiologists, hospitals, and others conducting hearing tests.

Parents paid for about 3.7% of births (percentage of self-paid births plus births for which the payor was unknown) in Arizona in 2012, according to data from the Department's 2012 *Health Status and Vital Statistics* publication. In FY 2013, parents were billed for 2,641 second specimens, and the Department collected \$105,622 from these parents. The Department anticipates that in upcoming years, if the rate of self-paid births declines slightly due to the Affordable Care Act, parents as a whole may be billed an extra \$55,000 and pay an extra \$50,000 for approximately 2,200 second specimens due to the fee increase, and the cost to an individual parent for increased fees for second specimens would be minimal. The Department anticipates that a parent of a baby with a third-party payor may incur minimal costs associated with an increase in insurance premiums if the third-party payor passes costs associated with the fee increase on to policyholders. The continuation of critical testing and follow-up activities and the changes made possible by the fee increase to address critical issues are expected to provide a significant benefit to the parent of a baby tested through newborn screening or whose hearing test results are reported to the Department.

10. A description of any changes between the proposed rulemaking, to include supplemental notices, and the final rulemaking:

Minor technical and grammatical changes, including the references to the definitions of "admitted" and "hospital," were made by the Department and at the suggestion of staff of the Council to improve clarity.

11. An agency's summary of the public stakeholder comments made about the rulemaking and the agency response to the comments:

The Department received six written comments asking the Department to include the testing for critical congenital heart defects (CCHD) into NBS. The Department is considering the addition of CCHD at a future date after discussing the possible addition with stakeholders and determining the impact the addition may have on the stakeholders. No changes are being made to the rules on the basis of the comments. The Department held an oral proceeding for the proposed rules on February 12, 2014, at which there were no attendees.

12. All agencies shall list any other matters prescribed by statute applicable to the specific agency or to any specific rule or class of rules. Additionally, an agency subject to Council review under A.R.S. §§ 41-1052 and 41-1055 shall respond to the following questions:

a. Whether the rule requires a permit, whether a general permit is used and, if not, the reasons why a general permit is not used:

The rule does not require a permit.

b. Whether a federal law is applicable to the subject of the rule, whether the rule is more stringent than federal law and, if so, citation to the statutory authority to exceed the requirements of federal law:

Not applicable

c. Whether a person submitted an analysis to the agency that compares the rule's impact of the competitiveness of business in this state to the impact on business in other states:

No business competitiveness analysis was received by the Department.

13. A list of any incorporated by reference material as specified in A.R.S. § 41-1028 and its location in the rule:

Not applicable

14. Whether the rule was previously made, amended or repealed as an emergency rule. If so, cite the notice published in the Register as specified in R1-1-409(A). Also, the agency shall state where the text was changed between the

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emergency and the final rulemaking packages:

The rule was not previously made, amended, or repealed as an emergency rule.

15. The full text of the rules follows:

TITLE 9. HEALTH SERVICES

**CHAPTER 13. DEPARTMENT OF HEALTH SERVICES
HEALTH PROGRAMS SERVICES**

ARTICLE 2. NEWBORN AND INFANT SCREENING

Section

- R9-13-201. Definitions
- R9-13-202. Bloodspot Tests for Congenital Disorders
- R9-13-203. General Requirements for Newborn and Infant Bloodspot Tests
- R9-13-204. First Specimen Collection
- R9-13-205. Second Specimen Collection
- R9-13-206. Reporting Requirements for Specimens
- R9-13-207. Reporting Requirements for Hearing Test Results
- R9-13-208. Fees

ARTICLE 2. NEWBORN AND INFANT SCREENING

R9-13-201. Definitions

In this Article, unless otherwise specified:

1. "Abnormal result" means an outcome that deviates from the range of values established by the Department for an analysis performed as part of a bloodspot test, or for a hearing test.
2. ~~"Admitted Admission" or "admitted"~~ means the same as in A.A.C. ~~R9-10-201~~ R9-10-101.
3. "AHCCCS" means the Arizona Health Care Cost Containment System.
4. "Argininosuccinic acidemia" means a congenital disorder characterized by an inability to metabolize the amino acid argininosuccinic acid due to defective argininosuccinate lyase activity.
5. "Arizona State Laboratory" means the entity operated according to A.R.S. § 36-251.
- ~~5-6. "Audiological equipment" means instruments~~ an instrument used to help determine the presence, type, or degree of hearing loss by:
 - a. Providing ear-specific and frequency-specific stimuli to an individual; or
 - b. ~~measure a~~ Measuring an individual's physiological response to stimuli ~~determine the presence, type, or degree of hearing loss.~~
- ~~6-7. "Audiologist" means an individual licensed under A.R.S. Title 36, Chapter 17~~ the same as in A.R.S. § 36-1901.
- ~~7-8. "Beta-ketothiolase deficiency" means a congenital disorder characterized by an inability to metabolize 2-methyl-acetoacetyl-CoA due to defective mitochondrial acetoacetyl-CoA thiolase activity.~~
- ~~8-9. "Biotinidase deficiency" means a congenital disorder characterized by defective biotinidase activity that causes abnormal biotin metabolism.~~
- ~~9-10. "Birth center" means a health care facility that is not a hospital and is organized for the sole purpose of delivering newborns.~~
- ~~10-11. "Blood sample" means capillary or venous blood, but not cord blood, applied to the filter paper of a specimen collection kit.~~
- ~~11-12. "Bloodspot test" means multiple laboratory analyses performed on a blood sample to detect~~ screen for the presence of congenital disorders listed in R9-13-202.
- ~~12-13. "Carnitine uptake defect" means a congenital disorder characterized by a decrease in the amount of free carnitine due to defective sodium ion-dependent carnitine transporter OCTN2 activity.~~
- ~~13-14. "Citrullinemia" means a congenital disorder characterized by an inability to convert the amino acid citrulline and aspartic acid into argininosuccinic acid due to defective argininosuccinate synthetase activity.~~
- ~~14-15. "Classic galactosemia" means a congenital disorder characterized by abnormal galactose metabolism due to defective galactose-1-phosphate uridylyltransferase activity.~~
- ~~15-16. "Congenital adrenal hyperplasia" means a congenital disorder characterized by decreased cortisol production and increased androgen production due to defective 21-hydroxylase activity.~~
- ~~16-17. "Congenital disorder" means an abnormal condition present at birth, as a result of heredity or environmental factors, that impairs normal physiological functioning of a human body.~~
- ~~17-18. "Congenital hypothyroidism" means a congenital disorder characterized by deficient thyroid hormone production.~~

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- 18-19. "Cystic fibrosis" means a congenital disorder caused by defective functioning of a transmembrane regulator protein and characterized by damage to and dysfunction of various organs, such as the lungs, pancreas, and reproductive organs.
- 19-20. "Department" means the Arizona Department of Health Services.
- 20-21. "Discharge" means the termination of inpatient services to a newborn or an infant.
- 21-22. "Disorder" means a disease or medical condition that may be identified by a laboratory analysis.
- 22-23. "Document" means to establish and maintain information in written, photographic, electronic, or other permanent form.
- 23-24. "Educational materials" means printed or electronic information provided by the Department, explaining newborn and infant screening, any of the congenital disorders listed in R9-13-202, or hearing loss.
- 24-25. "Electronic" means the same as in A.R.S. § 44-7002.
- 25-26. "First specimen" means the initial specimen that is collected from a newborn who is less than five days of age and sent to the ~~screening laboratory~~ Arizona State Laboratory for testing and recording of demographic information.
- 26-27. "Glutaric acidemia type I" means a congenital disorder characterized by an accumulation of glutaric acid due to defective glutaryl-CoA dehydrogenase activity.
- 27-28. "Guardian" means an individual appointed by a court under A.R.S. Title 14, Chapter 5, Article 2.
- 28-29. "Health care facility" means a health care institution defined in A.R.S. § 36-401 where obstetrical care or newborn care is provided.
- 29-30. "Health care provider" means a physician, physician assistant, registered nurse practitioner, or midwife.
- 30-31. "Health-related services" means the same as in A.R.S. § 36-401.
- 31-32. "Hearing test" means an evaluation of ~~both ears of a newborn or infant~~ each of a newborn's or an infant's ears, using audiological equipment; ~~for the presence, type, or degree of hearing loss to:~~
- a. Screen the newborn or infant for a possible hearing loss;
 - b. Determine that the newborn or infant does not have a hearing loss; or
 - c. Diagnose a hearing loss in the newborn or infant, including, if applicable, determining the type or degree of hearing loss.
- 32-33. "Hemoglobin S/Beta-thalassemia" means a sickle cell disease in which an individual has one sickle cell gene and one gene for beta thalassemia, another inherited hemoglobinopathy.
- 33-34. "Hemoglobin S/C disease" means a sickle cell disease in which an individual has one sickle cell gene and one gene for another inherited hemoglobinopathy called hemoglobin C.
- 34-35. "Hemoglobinopathy" means a congenital disorder characterized by abnormal production, structure, or functioning of hemoglobin.
- 35-36. "Home birth" means delivery of a newborn, outside a health care facility, when the newborn is not hospitalized within 72 hours of delivery.
- 36-37. "Homocystinuria" means a congenital disorder characterized by abnormal methionine and homocysteine metabolism due to defective cystathione- β -synthase activity.
- 37-38. "Hospital" means the same as in A.A.C. ~~R9-10-201~~ R9-10-101.
- 38-39. "Hospital services" means the same as in A.A.C. R9-10-201.
- 39-40. "3-Hydroxy-3-methylglutaric aciduria" means a congenital disorder characterized by the accumulation of 3-hydroxy-3-methylglutaric acid due to a defective 3-hydroxy-3-methylglutaryl-CoA lyase activity.
- 40-41. "Identification code" means a unique set of numbers or letters, or a unique set of both numbers and letters, assigned by the Department to a health care facility, a health care provider, an audiologist, or another person submitting specimen collection kits to the ~~screening laboratory~~ Arizona State Laboratory or hearing test results to the Department.
- 41-42. "Infant" means the same as in A.R.S. § 36-694.
- 42-43. "Inpatient" means an individual who:
- a. Is admitted to a hospital,
 - b. Receives hospital services for 24 consecutive hours, or
 - c. Is admitted to a birth center.
- 43-44. "Inpatient services" means medical services, nursing services, or other health-related services provided to an inpatient in a health care facility.
- 44-45. "Isovaleric acidemia" means a congenital disorder characterized by an accumulation of isovaleric acid due to defective isovaleryl-CoA dehydrogenase activity.
- 45-46. "Long-chain 3-hydroxy acyl-CoA dehydrogenase deficiency" means a congenital disorder characterized by an inability to metabolize fatty acids that are 12 to 16 carbon atoms in length due to defective long-chain 3-hydroxy acyl-CoA dehydrogenase activity.
- 46-47. "Maple syrup urine disease" means a congenital disorder of branched chain amino acid metabolism due to defective branched chain-keto acid dehydrogenase activity.
- 47-48. "Medical services" means the same as in A.R.S. § 36-401.
- 48-49. "Medium chain acyl-CoA dehydrogenase deficiency" means a congenital disorder characterized by an inability to

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- metabolize fatty acids that are 6 to 10 carbon atoms in length due to defective medium-chain acyl-CoA dehydrogenase activity.
- ~~49-50.~~ “3-Methylcrotonyl-CoA carboxylase deficiency” means a congenital disorder characterized by an accumulation of 3-methylcrotonyl-glycine due to defective 3-methylcrotonyl-CoA carboxylase activity.
- ~~50-51.~~ “Methylmalonic acidemia (Cbl A,B)” means a congenital disorder characterized by an accumulation of methylmalonic acid due to defective activity of methylmalonyl-CoA racemase or adenosylcobalamin synthetase.
- ~~51-52.~~ “Methylmalonic acidemia (mutase deficiency)” means a congenital disorder characterized by an accumulation of methylmalonic acid due to defective methylmalonyl-CoA mutase activity.
- ~~52-53.~~ “Midwife” means an individual licensed under A.R.S. Title 36, Chapter 6, Article 7, or certified under A.R.S. Title 32, Chapter 15.
- ~~53-54.~~ “Multiple carboxylase deficiency” means a congenital disorder characterized by an inability to transport or metabolize biotin that leads to defective activity of propionyl-CoA carboxylase, beta-methylcrotonyl-CoA carboxylase, and pyruvate carboxylase.
- ~~54-55.~~ “Newborn” means the same as in A.R.S. § 36-694.
- ~~55-56.~~ “Newborn care” means medical services, nursing services, and health-related services provided to a newborn.
- ~~56-57.~~ “Nursing services” means the same as in A.R.S. § 36-401.
- ~~57-58.~~ “Obstetrical care” means medical services, nursing services, and health-related services provided to a woman throughout her pregnancy, labor, delivery, and postpartum.
- ~~58-59.~~ “Organ” means a somewhat independent part of a human body, such as a salivary gland, kidney, or pancreas, which performs a specific function.
- ~~59-60.~~ “Parent” means a natural, adoptive, or custodial mother or father of a newborn or an infant.
- ~~61.~~ “Parenteral nutrition” means the feeding of an individual intravenously through the administration of a formula containing glucose, amino acids, lipids, vitamins, and minerals.
- ~~60-62.~~ “Person” means the state, a municipality, district, or other political subdivision, a cooperative, institution, corporation, company, firm, partnership, individual, or other legal entity.
- ~~61-63.~~ “Phenylketonuria” means a congenital disorder characterized by abnormal phenylalanine metabolism due to defective phenylalanine hydroxylase activity.
- ~~62-64.~~ “Physician” means an individual licensed under A.R.S. Title 32, Chapters 13, 14, 17, or 29.
- ~~63-65.~~ “Physician assistant” means an individual licensed under A.R.S. Title 32, Chapter 25.
- ~~64-66.~~ “Propionic acidemia” means a congenital disorder characterized by an accumulation of glycine and 3-hydroxypropionic acid due to defective propionyl-CoA carboxylase activity.
- ~~65-67.~~ “Registered nurse practitioner” means the same as in A.R.S. § 32-1601.
- ~~66.~~ “Screening laboratory” means an entity contracted with the Department under A.R.S. § 36-694(I) to perform the bloodspot test.
- ~~67-68.~~ “Second specimen” means a specimen that is sent to the ~~screening laboratory~~ Arizona State Laboratory for testing and recording of demographic information, after being collected:
- From a newborn after a first specimen; or
 - From an individual at least five days and not older than one year of age, regardless of whether a first specimen was collected.
- ~~68-69.~~ “Sickle cell anemia” means a sickle cell disease in which an individual has two sickle cell genes.
- ~~69-70.~~ “Sickle cell disease” means a hemoglobinopathy characterized by an abnormally shaped red blood cell resulting from the abnormal structure of the protein hemoglobin.
- ~~70-71.~~ “Sickle cell gene” means a unit of inheritance that is involved in producing an abnormal type of the protein hemoglobin, in which the amino acid valine is substituted for the amino acid glutamic acid at a specific location in the hemoglobin.
- ~~71-72.~~ “Specimen” means a blood sample obtained from and demographic information about a newborn or an infant.
- ~~72-73.~~ “Specimen collection kit” means a strip of filter paper for collecting a blood sample attached to a form for obtaining the information specified in R9-13-203(A)(3) about a newborn or an infant.
- ~~73.~~ “Test” means a laboratory analysis performed on body fluid, tissue, or excretion to determine the presence or absence of a disorder.
74. “Transfer” means a health care facility discharging a newborn and sending the newborn to a hospital for inpatient medical services without the intent that the patient will be returned to the sending health care facility.
75. “Transfusion” means the infusion of blood or blood products into the body of an individual.
76. “Trifunctional protein deficiency” means a congenital disorder characterized by an inability to metabolize fatty acids that are 12 to 18 carbon atoms in length due to defective mitochondrial trifunctional protein activity.
77. “Tyrosinemia type I” means a congenital disorder characterized by an accumulation of the amino acid tyrosine due to defective fumarylacetoacetate hydrolase activity.
78. “Verify” means to confirm by obtaining information through a source such as the newborn screening program, a health care provider, a health care facility, or a documented record.

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79. "Very long-chain acyl-CoA dehydrogenase deficiency" means a congenital disorder characterized by an inability to metabolize fatty acids that are 14 to 18 carbon atoms in length due to defective very long-chain acyl-CoA dehydrogenase activity.
80. "Working day" means 8:00 a.m. through 5:00 p.m. Monday through Friday, excluding state holidays.

R9-13-202. Bloodspot Tests for Congenital Disorders

A bloodspot test shall ~~include laboratory analyses~~ screen for the following congenital disorders:

1. 3-Hydroxy-3-methylglutaric aciduria.
2. 3-Methylcrotonyl-CoA carboxylase deficiency.
- ~~1-3.~~ Argininosuccinic acidemia,
4. Beta-ketothiolase deficiency.
- ~~2-5.~~ Biotinidase deficiency,
6. Carnitine uptake defect.
- ~~3-7.~~ Citrullinemia,
- ~~4-8.~~ Classic galactosemia,
- ~~5-9.~~ Congenital adrenal hyperplasia,
- ~~6-10.~~ Congenital hypothyroidism,
11. Cystic fibrosis.
12. Glutaric acidemia type I.
- ~~7-13.~~ Hemoglobin S/Beta-thalassemia,
- ~~8-14.~~ Hemoglobin S/C disease,
- ~~9-15.~~ Homocystinuria,
16. Isovaleric acidemia.
17. Long-chain 3-hydroxy acyl-CoA dehydrogenase deficiency.
- ~~10-18.~~ Maple syrup urine disease,
19. Medium chain acyl-CoA dehydrogenase deficiency.
20. Methylmalonic acidemia (Cbl A,B).
21. Methylmalonic acidemia (mutase deficiency).
22. Multiple carboxylase deficiency.
- ~~11-23.~~ Phenylketonuria,
24. Propionic acidemia.
- ~~12-25.~~ Sickle cell anemia,
26. Trifunctional protein deficiency.
- ~~13-27.~~ Tyrosinemia type I, and
28. Very long-chain acyl-CoA dehydrogenase deficiency.
- ~~14-3~~ Methylcrotonyl CoA carboxylase deficiency;
15. 3-Hydroxy-3-methylglutaric aciduria;
16. Beta-ketothiolase deficiency;
17. Carnitine uptake defect;
18. Glutaric acidemia type I;
19. Isovaleric acidemia;
20. Long-chain 3-hydroxy acyl-CoA dehydrogenase deficiency;
21. Medium chain acyl-CoA dehydrogenase deficiency;
22. Methylmalonic acidemia (Cbl A,B);
23. Methylmalonic acidemia (mutase deficiency);
24. Multiple carboxylase deficiency;
25. Propionic acidemia;
26. Trifunctional protein deficiency;
27. Very long-chain acyl-CoA dehydrogenase deficiency; and
28. Cystic fibrosis.

R9-13-203. General Requirements for Newborn and Infant Bloodspot Tests

- A. When a bloodspot test is ordered for a newborn or an infant, a health care facility's designee, a health care provider, or the health care provider's designee shall:
1. Only use a specimen collection kit supplied by the Department;
 2. Collect a blood sample from the newborn or infant on a specimen collection kit;
 3. Complete the following information on the specimen collection kit:
 - a. The newborn's or infant's name, gender, race, ethnicity, medical record number, and, if applicable, AHCCCS identification number;
 - b. The newborn's or infant's type of food or food source;

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- c. Whether the newborn or infant is from a single or multiple birth;
 - d. If the newborn or infant is from a multiple birth, the birth order of the newborn or infant;
 - e. Whether the newborn or infant has a medical condition that may affect the bloodspot test results;
 - f. Whether the newborn or infant received ~~antibiotics or~~ a blood transfusion and, if applicable, the date of the last blood transfusion;
 - ~~g. The method of blood sample collection;~~
 - ~~h-g.~~ The date and time of birth, and the newborn's or infant's weight at birth;
 - ~~i-h.~~ The date and time of blood sample collection, and the newborn's or infant's weight when the blood sample is collected;
 - ~~j-i.~~ The ~~name and~~ identification code or the name and address of the health care facility or health care provider submitting the specimen collection kit;
 - ~~k-j.~~ The name, ~~identification code, and address, and telephone number or the identification code~~ of the health care provider responsible for the management of medical services provided to the newborn or infant;
 - ~~l-k.~~ Except as provided in subsection (A)(3)(m) (A)(3)(l), the mother's first and last names, date of birth, name before first marriage, mailing address, ~~phone~~ telephone number, and if applicable, AHCCCS identification number; and
 - ~~m-l.~~ If the newborn's or infant's mother does not have physical custody of the newborn or infant, the first and last names, mailing address, and ~~phone~~ telephone number of the person who has physical custody of the newborn or infant; and
4. Submit the specimen collection kit to the ~~screening laboratory~~ Arizona State Laboratory no later than 24 hours or the next working day after the blood sample is collected.
- B.** A health care facility or a health care provider submitting a first specimen to the ~~screening laboratory~~ Arizona State Laboratory shall pay the Department the fee in R9-13-208(A).
- C.** A person who submits a second specimen to the ~~screening laboratory~~ Arizona State Laboratory shall:
- 1. Pay the fee in R9-13-208(B) to the Department, or
 - 2. Provide the following information to the ~~screening laboratory~~ Arizona State Laboratory for billing purposes:
 - a. The name, mailing address, and ~~phone~~ telephone number of the newborn's or infant's parent or the individual responsible for paying, if not the parent; and
 - b. If the individual responsible for paying has health care insurance for the newborn or infant, information about the health care insurance, including:
 - i. The policyholder's name;
 - ii. The name and billing address of the health care insurance company;
 - iii. The member identification number;
 - iv. The group number, if applicable; and
 - v. The effective date of the health care insurance; or
 - c. That the individual responsible for paying has no health care insurance for the newborn or infant.
- D.** When a health care insurance company or an individual responsible for paying is identified as specified in subsection (C)(2), the health care insurance company or the individual responsible for paying shall pay the Department the fee in R9-13-208(B).
- E.** ~~The screening laboratory shall perform a bloodspot test on a blood sample from a specimen collection kit if:~~
- ~~1. The blood sample on the specimen collection kit:~~
 - ~~a. Contains a sufficient quantity of blood to complete the bloodspot test;~~
 - ~~b. Is not clotted or layered;~~
 - ~~c. Does not have serum rings;~~
 - ~~d. Is not diluted or discolored;~~
 - ~~e. Will elute from the filter paper;~~
 - ~~f. Has not been applied to both sides of the filter paper; and~~
 - ~~g. Is not contaminated;~~
 - ~~2. The filter paper on the specimen collection kit is not contaminated, scratched, or abraded;~~
 - ~~3. The information on the specimen collection kit is sufficient to identify:~~
 - ~~a. The newborn or infant; and~~
 - ~~b. The person who ordered the bloodspot test or caused the bloodspot test to be ordered; and~~
 - ~~4. The screening laboratory receives the specimen collection kit within 14 days after the blood sample is collected.~~
- F.E.** When a home birth not attended by a health care provider is reported to a local registrar, a deputy local registrar, or the state registrar under A.R.S. § 36-333:
- 1. The local registrar, deputy local registrar, or state registrar shall notify the local health department of the county where the birth occurred; and
 - 2. The local health department's designee shall collect a specimen from the newborn or infant according to the requirements in R9-13-204(A)(2) or R9-13-205(C).
- G.F.** A health care facility's designee, a health care provider, or the health care provider's designee shall ensure that:

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1. Educational materials are provided to the parent or guardian of a newborn or an infant for whom a bloodspot test is ordered, and
2. The newborn's or infant's parent or guardian is informed of the requirement for a second specimen if the second specimen has not been collected.

H.G. For a home birth, a health care provider or the health care provider's designee shall provide educational materials to the parent or guardian of a newborn or an infant for whom a bloodspot test is ordered.

R9-13-204. First Specimen Collection

- A.** When a newborn is born in a hospital, the hospital's designee shall collect a first specimen from the newborn according to whichever of the following occurs first:
 1. ~~Unless specified otherwise by a physician, physician assistant, or registered nurse practitioner. Before before administering a transfusion, unless specified otherwise by a physician, physician assistant, or registered nurse practitioner or parenteral nutrition;~~
 2. When the newborn is at least 24 but not more than 72 hours old; or
 3. Before the newborn is discharged, unless the newborn:
 - a. Is transferred to another hospital before the newborn is 48 hours old; or
 - b. Dies before the newborn is 72 hours old.
- B.** If a newborn is admitted or transferred to a hospital before the newborn is 48 hours old, the receiving hospital's designee shall:
 1. Verify that the first specimen was collected before admission or transfer, or
 2. Collect a first specimen from the newborn according to the requirements in subsection (A).
- C.** When a newborn is born in a birth center, the birth center's designee shall collect a first specimen from the newborn according to subsections (A)(1) or (A)(2).
- D.** For a home birth attended by a health care provider, the health care provider or the health care provider's designee shall collect a first specimen from the newborn according to the requirements in subsection (A)(2).

R9-13-205. Second Specimen Collection

- A.** After a newborn's or an infant's discharge from a health care facility or after a home birth, a health care provider or the health care provider's designee shall:
 1. Collect a second specimen from ~~a~~ the newborn or infant not older than one year of age:
 - ~~a. When the newborn is at least 5 but not more than 10 days old; or~~
 - ~~b. At at the time of a the newborn's or infant's first visit to the health care provider; or~~
 2. Verify that a health care facility or different health care provider has collected ~~the a~~ second specimen from the newborn or infant.
- B.** If a newborn is an inpatient of a health care facility at 5 days of age, the health care facility's designee shall collect a second specimen from the newborn:
 1. When the newborn is at least 5 but not more than 10 days old; or
 2. If the newborn is discharged from the health care facility when the newborn is at least 5 but not more than 10 days old, before discharge.
- C.** For a home birth that is not attended by a health care provider, a local health department's designee shall collect a specimen from a newborn or an infant if the local health department's designee has not verified that a second specimen has ~~not~~ already been collected from the newborn or infant.
- D.** ~~A health care provider or the health care provider's designee shall ensure that a subsequent specimen is ordered for a newborn or child one year of age or less, according to the requirements in R9-13-203, when the health care provider or the health care provider's designee:~~
 - ~~1. Begins providing health care to the newborn or child, and~~
 - ~~2. Cannot verify the results of a bloodspot test that was conducted on a second specimen from the newborn or child.~~

R9-13-206. Reporting Requirements for Specimens

- A.** The screening laboratory shall:
 1. Report in written or electronic format:
 - a. The results of a bloodspot test on a specimen; and
 - b. For a specimen that does not meet the requirements for testing specified in R9-13-203(E):
 - i. That the bloodspot test was not performed on the specimen; and
 - ii. The reason the bloodspot test was not performed; and
 2. Send the report to:
 - a. The health care provider identified on the specimen collection kit;
 - b. If applicable, the health care facility identified on the specimen collection kit; and
 - c. The Department.
- B.** The screening laboratory shall begin reporting bloodspot test results for the congenital disorders specified in:
 1. R9-13-202 (1) through (13), on the effective date of these rules;

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2. ~~R9-13-202(14) through (27), no later than August 31, 2006; and~~
3. ~~R9-13-202(28), no later than June 30, 2007.~~

A. The Arizona State Laboratory shall report, in written or electronic format, to the health care provider and, if applicable, health care facility identified on a specimen collection kit:

1. The results of a bloodspot test on a specimen; or
2. For a specimen that does not meet quality standards established by the Arizona State Laboratory in compliance with 42 CFR § 493.1200:
 - a. That a bloodspot test was not performed on the specimen; and
 - b. The reason the bloodspot test was not performed.

~~**B.**~~ **A** health care facility's designee, a health care provider, or the health care provider's designee, who orders a subsequent test on a newborn or an infant in response to an abnormal result on a bloodspot test, shall send the results of the subsequent test in writing to the Department, if the subsequent test is not performed by the ~~screening laboratory~~ Arizona State Laboratory.

~~**C.**~~ **B**loodspot test results are confidential subject to the disclosure provisions of 9 A.A.C. 1, Article 3, and A.R.S. §§ 12-2801 and 12-2802.

R9-13-207. Reporting Requirements for Hearing Test Results

A. When an initial hearing test is performed on a newborn, a health care facility's designee, a health care provider, or the health care provider's designee shall provide to the Department, as specified in subsection (E), the following information:

1. The newborn's name, date of birth, gender, and medical record number;
2. Whether the newborn is from a single or multiple birth;
3. If the newborn is from a multiple birth, the birth order of the newborn;
4. ~~The newborn's mother's first and last names and date of birth of the newborn's mother;~~
5. ~~The name and identification code of the health care facility or health care provider submitting the hearing test results;~~
6. ~~The name and identification code of the health care facility of birth;~~
6. If the initial hearing test was not performed by the health care facility of birth, either:
 - a. The name and identification code of the health care facility where the initial hearing test was performed, or
 - b. The name and telephone number of the health care provider who performed the initial hearing test;
7. The name of the health care provider responsible for the coordination of medical services for the newborn;
8. The date of the hearing test;
9. Whether or not the hearing test was performed when the newborn was an inpatient;
10. The audiological equipment used for the hearing test and the type of hearing test performed;
11. The hearing test result for each of the newborn's ears; and
12. The name, address, and ~~phone~~ telephone number of the contact person for the health care facility or health care provider.

B. In addition to the information in subsection (A), if the reported results of an initial hearing test on a newborn include an abnormal result, a health care facility's designee, a health care provider, or the health care provider's designee shall provide to the Department, as specified in subsection (E), the following information:

1. The newborn's race, ethnicity, and if applicable, AHCCCS identification number;
2. Except as provided in subsection (B)(3), the mother's ~~date of birth~~, name before first marriage, mailing address, and ~~phone~~ telephone number;
3. If the newborn's mother does not have physical custody of the newborn, the first and last names, mailing address, and ~~phone~~ telephone number of the person who has physical custody of the newborn;
4. The name of the health care provider who will be responsible for the coordination of medical services for the newborn after the newborn is discharged from the health care facility, if different from the health care provider specified in subsection (A)(7); and
5. The name and ~~phone~~ telephone number of the person to whom the newborn's mother or other person who has physical custody of the newborn was referred for a subsequent hearing test.

C. When a hearing test is performed on a newborn or an infant after an initial hearing test, the designee of the health care facility, health care provider, or other person that performs the subsequent hearing test shall provide to the Department, as specified in subsection (E), the following information:

1. The newborn's or infant's name, date of birth, and gender;
2. Whether the newborn or infant is from a single or multiple birth;
3. If the newborn or infant is from a multiple birth, the birth order of the newborn or infant;
4. ~~The newborn's mother's first and last names and date of birth of the newborn's or infant's mother;~~
5. ~~The name of the health care facility where the initial hearing test was performed, or the name and address of the health care provider who performed the initial hearing test;~~
6. ~~The name of the health care facility of birth;~~
6. If the initial hearing test was not performed by the health care facility of birth, either:
 - a. The name of the health care facility where the initial hearing test was performed, or

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- b. The name and telephone number of the health care provider who performed the initial hearing test;
 7. The name, telephone number, and identification code of the person submitting the subsequent hearing test results;
 8. The date of the subsequent hearing test;
 9. The audiological equipment used for the subsequent hearing test; ~~and the~~
 10. The type of hearing test performed;
 - ~~10-11.~~ The result, including a quantitative result if applicable, for each of the newborn's or infant's ears on the subsequent hearing test; and
 12. If the subsequent hearing test was performed by an audiologist or a physician to determine that the newborn or infant does not have a hearing loss or diagnose a hearing loss in the newborn or infant:
 - a. Whether the newborn or infant has a hearing loss and, if so, the type and degree of hearing loss; and
 - b. A copy of the narrative that describes the hearing test performed on the newborn or infant to determine that the newborn or infant does not have a hearing loss or diagnose a hearing loss in the newborn or infant, the results of the hearing test, and the analysis of the hearing test results by the audiologist or physician who performed the hearing test; and
 - ~~11-13.~~ The name, address, and ~~phone~~ telephone number of the contact person for the health care facility, health care provider, or other person that performed the subsequent hearing test, if different from the person specified in subsection (C)(7).
- D. In addition to the information in subsection (C), if the reported results of a subsequent hearing test on a newborn or an infant include an abnormal result, the person submitting the report on the subsequent hearing test shall provide to the Department, as specified in subsection (E), the following ~~information~~:
1. Except as provided in subsection (D)(2), the ~~newborn's or infant's mother's mailing address and phone number mail-~~ ing address and telephone number of the newborn's or infant's mother;
 2. If the newborn's or infant's mother does not have physical custody of the newborn or infant, the first and last names, mailing address, and ~~phone~~ telephone number of the person who has physical custody of the newborn or infant;
 3. The name of the health care provider who is responsible for the coordination of medical services for the newborn or infant; and
 4. If applicable, the name and ~~phone~~ telephone number of the person to whom the newborn's or infant's parent was referred for further hearing tests, evaluation services, specialty care, or early intervention.
- E. A health care facility's designee, health care provider, health care provider's designee, or other person required to report under subsections (A), (B), (C), or (D) shall submit, in an electronic format specified by the Department, the information specified in subsections (A), (B), (C), or (D) for hearing tests performed each week by the sixth day of the subsequent week.
- R9-13-208. Fees**
- A. The fee for a first specimen is \$30.00.
 - B. The fee for a second specimen is ~~\$40.00~~ \$65.00.

NOTICE OF FINAL RULEMAKING

TITLE 19. ALCOHOL, HORSE AND DOG RACING, LOTTERY, AND GAMING

CHAPTER 3. ARIZONA STATE LOTTERY COMMISSION

Editor's Note: The following Notice of Final Rulemaking was reviewed per Executive Order 2012-03 as issued by Governor Brewer. (See the text of the executive order on page 978.) The Governor's Office authorized the notice to proceed through the rulemaking process on July 18, 2013.

[R14-53]

PREAMBLE

1. Article, Part, or Section Affected (as applicable) Rulemaking Action
R19-3-202 Amend
2. Citations to the agency's statutory rulemaking authority to include both the authorizing statute (general) and the implementing statute (specific):
Authorizing statute: A.R.S. § 5-554(B)
Implementing statute: A.R.S. § 5-562
3. The effective date of the rules:
June 1, 2014

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4. Citations to all related notices published in the Register as specified in R1-1-409(A) that pertain to the record of the final rulemaking package:

Notice of Rulemaking Docket Opening: 19 A.A.R. 2858, September 20, 2013

Notice of Proposed Rulemaking: 19 A.A.R. 3572, November 15, 2013

5. The agency's contact person who can answer questions about the rulemaking:

Name: Jeff Hatch-Miller, Executive Director

Address: Arizona State Lottery
4740 E. University Drive
Phoenix, AZ 85034

Telephone: (480) 921-4505

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or

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6. An agency's justification and reason why a rule should be made, amended, repealed, or renumbered, to include an explanation about the rulemaking:

Article 2, Retailers, prescribes the requirements and procedures for Arizona retail businesses that sell Lottery game products. The rules require a license applicant to submit fingerprints in order to perform a criminal background check. The Department of Public Safety (DPS) has historically provided this service for the Lottery. However, DPS has established a new program that will make compliance difficult for both the Lottery and prospective retailers. Through a comparison of results, the Lottery found that criminal background information obtained from a database service was equivalent to that received from DPS. The rules are being amended to remove fingerprint requirements from the licensing process.

7. A reference to any study relevant to the rule that the agency reviewed and either relied on or did not rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

The Lottery utilized two different approaches for securing criminal background information to determine if results were comparable. One method continued to use the fingerprint processing services of DPS and the other involved using a public records database system to obtain relevant information. Both methods were used for employment background checks over a period of approximately eight months, and a comparison indicated that results were equivalent. This information is available at the Lottery's Phoenix office.

8. A showing of good cause why the rulemaking is necessary to promote a statewide interest if the rulemaking will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

9. A summary of the economic, small business, and consumer impact:

1. Identification of the proposed rulemaking.

Rules for Article 2, Retailers, describe various requirements and procedures for retail businesses that sell Lottery game products. The Lottery's existing retailer rules require a license applicant to submit fingerprints in order to perform a criminal background check. The Department of Public Safety (DPS) has been performing this service for the Lottery, but recently instituted a new compliance program for agencies requesting criminal history record information for non-criminal justice purposes, such as licensing. The new standards and chain of custody requirements will make it difficult and time-consuming for the applicant and the Lottery to comply with the new policy. This rulemaking removes licensing provisions pertaining to fingerprint requirements; no new rules are necessary.

Conduct and frequency of occurrence: There is no specific conduct this rulemaking is designed to change.

2. Persons who will be directly affected by, bear the costs of, or directly benefit from the proposed rulemaking.

The Lottery anticipates this rulemaking will primarily impact the agency and prospective Lottery retailers.

3. Cost-benefit Analysis:

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a. Probable costs and benefits to the implementing agency and other agencies directly affected by the implementation and enforcement of the proposed rulemaking, including the number of new full-time employees necessary to implement and enforce the proposed rules.

Costs to the Lottery related to this rulemaking include application/licensing expenses; retailers pay a license fee that allows the Lottery to recover these costs. No fee changes are requested as a result of these rules. The Lottery benefits from the rulemaking by avoiding time-consuming training that would strain limited staff resources. The Lottery also benefits from eliminating delays in the licensing process.

The Lottery has historically checked criminal background information for potential retailers as well as license renewals by submitting fingerprints to DPS for processing. DPS has recently adopted FBI practices and policies for agencies requesting criminal history information. The new standards and chain of custody (protecting against fraud as fingerprints move through the process) would require extensive training, a difficult undertaking with the Lottery's present staffing levels.

Criminal background information can also be obtained through the use of a public records database service, without the need for fingerprints. Over the past 8 months, the Lottery conducted employment background checks using a dual system of fingerprints through DPS and "Lexis Nexis Accurint," a public records database. The database gathers information from various courts, property records, and tax assessments. The Lottery's investigations division conducted a comparison of results from both sources and found that Lexis Nexis Accurint provides criminal background information that is just as reliable and more complete. The dual process test ensures there is a factual basis for determining that the replacement of a fingerprint-based criminal background check with a database criminal background check provides the same information to the Lottery. Almost all background checks contain some type of violation due to the fact that the report shows all activity, including non-criminal items such as traffic violations. The Lottery denies 2-3 applications per year as a result of background checks.

An ancillary benefit of a database service is increased efficiency in the licensing process. It takes up to 30 days to receive information back from DPS as compared to almost immediate turnaround from the database system. This should result in a reduced time frame to process license applicants. In FY13, the average application processing time was 35 days.

The cost to use the public records database is within \$1 of the cost to use DPS. As a result, no increase to the license fee is warranted. In addition, the change from DPS to Lexis Nexis Accurint will eliminate the need to recoup the additional DPS fingerprint charge for applicants that resided outside Arizona within the last 10 years. In FY13, the Lottery processed 195 new retailer license applications and renewed 320 license applications. Corporate chain stores submit one application for all store locations.

Other Agencies: The only other agency impacted by the rulemaking is the Department of Public Safety. DPS will no longer receive the fee for processing Lottery fingerprint requests, but this revenue was not significant in any given year. In FY13, the Lottery paid DPS approximately \$9,000 for its services.

FTE Requirements: The Lottery does not anticipate the need to hire any additional full-time employees; current staff resources will be used to implement the proposed rules.

b. Probable costs and benefits to a political subdivision of this state directly affected by the implementation and enforcement of the proposed rulemaking.

Other than the impact outlined above for DPS, this rulemaking should not have any impact on political subdivisions of the state.

c. Probable costs and benefits to businesses directly affected by the proposed rulemaking, including any anticipated effect on the revenues or payroll expenditure of employers who are subject to the proposed rulemaking.

Businesses impacted by these rules are retail establishments that choose to apply for a license to sell Lottery products. Lottery retailers are also the only small businesses impacted by this rulemaking. The rules are expected to benefit retailers, both large and small.

Costs to retailers include application/licensing fees and any administrative costs associated with selling Lottery products. There are no additional costs as a result of this rulemaking. The basic license fee remains unchanged, and eliminating the fingerprint requirement means applicants will save any out-of-pocket fees paid to have this performed. If relevant, applicants will also no longer incur the supplemental fingerprint fee associated with residing outside Arizona within the past 10 years.

Retailer license applicants will benefit from a more efficient Lottery licensing process. A faster turnaround time for becoming a licensed retailer translates to the opportunity to earn commissions earlier. In FY13, Lottery retailers earned over \$46 million in game commissions. There are currently about 2900 licensed Lottery retailers.

The Lottery has a large number of retailers and the licensing process should be as straightforward as possible while still protecting the interests of the Lottery and the state. The new compliance standards through DPS will be burdensome for Lottery license applicants; as a result, some applicants could choose not to proceed with the licensing process. Replacing the traditional fingerprint process with the use of a database system simplifies the application process and lessens the burden for Lottery retailers, while still maintaining the integrity of licensing procedures.

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4. Probable impact on private and public employment in businesses, agencies, and political subdivisions of the state directly affected by the proposed rulemaking.

This rulemaking will not have any identifiable impact on private and public employment.

5. Probable impact of the rulemaking on small business.

a. Identification of the small businesses subject to the rulemaking.

Small businesses impacted by these rules are also retail establishments that choose to apply for a license to sell Lottery products. The impact on these businesses should be positive as well. The elimination of the fingerprint requirement benefits all potential retailers, but small retail applicants may derive a greater benefit from the associated cost and time savings since these retailers are more likely to have limited administrative and personnel resources.

b. Administrative and other costs required for compliance with the rulemaking.

Any administrative costs incurred to comply with application requirements will apply to all businesses, including small businesses. However, as described above, this rulemaking reduces administrative costs associated with the fingerprint licensing requirement.

c. A description of methods that may be used to reduce the impact on small businesses and reasons for the agency's decision to use or not use each method.

Not applicable to this rulemaking; the rules are expected to have a positive impact on small businesses.

6. Probable cost and benefit to private persons and consumers who are directly affected by the proposed rulemaking.

There are no identifiable costs to consumers or the general public associated with this rulemaking. Consumers who also enjoy playing Lottery games will continue to benefit from a variety of retail locations offering Lottery products.

7. Probable effect on state revenues.

Revenue generated from retailer license fees are deposited into the Lottery Fund. The rulemaking is expected to have a neutral impact on state revenues since license fees only allow the Lottery to recover the cost of providing the service. In FY13, the Lottery collected \$53,200 in license revenue.

A percentage of Lottery game revenue is returned to the state to fund various beneficiary programs as specified in A.R.S. § 5-572. Although an exact amount cannot be calculated, the state will benefit financially from any incremental revenues retailers generate as a result of a faster licensing turnaround time. The Lottery returned a record \$176.5 million to state beneficiaries in FY13.

8. Less intrusive or less costly alternative methods of achieving the purpose of the proposed rulemaking.

The Lottery is unaware of any other less intrusive or less costly methods for achieving the purpose of the rulemaking. A.R.S. § 5-562(A) provides broad authority for the Lottery to conduct background checks and the Lottery also has authority under Executive Order 81-2 to conduct a criminal history by submitting fingerprints. Advances in technology now provide practical alternatives for the Lottery to obtain criminal background information, with the added benefit of improved efficiency. As a result, fingerprints are no longer necessary as an application requirement.

Reduced license application requirements will minimize the burden on retailer applicants, while still providing the Lottery with necessary criminal background information. Similarly, the elimination of the fingerprint requirement will lessen the administrative burden for the Lottery. The Lottery does not require additional funding or personnel resources to implement the proposed rules.

9. Description of any data on which the rule is based.

The only data/information utilized with respect to the rules was a comparison of criminal background information received from DPS and a database service to ensure consistency and reliability of results.

10. A description of any changes between the proposed rulemaking, to include supplemental notices, and the final rulemaking:

There are no substantive changes between the proposed rules and the final rules. Grammatical, technical, and clarifying changes were made to the economic impact statement at the request of Governor's Regulatory Review Council staff. No changes were made to rule text.

11. An agency's summary of the public or stakeholder comments made about the rulemaking and the agency response to the comments:

No oral or written comments were received regarding the rulemaking.

12. All agencies shall list other matters prescribed by statute applicable to the specific agency or to any specific rule or class of rules. Additionally, an agency subject to Council review under A.R.S. §§ 41-1052 and 41-1055 shall respond to the following questions:

Not applicable

a. Whether the rule requires a permit, whether a general permit is used and if not, the reasons why a general per-

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mit is not used:

The implementing statutes of the Lottery require a licensing process rather than a general permit.

b. Whether a federal law is applicable to the subject of the rule, whether the rule is more stringent than federal law and if so, citation to the statutory authority to exceed the requirements of federal law:

There is no corresponding federal law that is applicable to the subject matter. The rules are based on state law.

c. Whether a person submitted an analysis to the agency that compares the rule's impact of the competitiveness of business in this state to the impact on business in other states:

No analysis was submitted.

13. A list of any incorporated by reference material as specified in A.R.S. § 41-1028 and its location in the rule:

None

14. Whether the rule was previously made, amended or repealed as an emergency rule. If so, cite the notice published in the Register as specified in R1-1-409(A). Also, the agency shall state where the text was changed between the emergency and the final rulemaking packages:

Not applicable

15. The full text of the rule follows:

TITLE 19. ALCOHOL, HORSE AND DOG RACING, LOTTERY, AND GAMING

CHAPTER 3. ARIZONA STATE LOTTERY COMMISSION

ARTICLE 2. RETAILERS

Section

R19-3-202. Retailer's Application for License

ARTICLE 2. RETAILERS

R19-3-202. Retailer's Application for License

All applicants shall provide the Director with the following to apply for a license to sell Lottery tickets:

1. A verified application on forms prescribed by the Director containing the following information:
 - a. The applicant's name, and if different, the trade name of the business premise, address of the physical location of the place of business, the mailing address if different, and phone number;
 - b. The applicant's current transaction privilege tax license number issued under A.R.S. § 42-5005 and federal taxpayer identification number issued by the Internal Revenue Service and recorded on Form W-9;
 - c. Certification that access to the applicant's business complies with the Americans with Disabilities Act;
 - d. Marketing and sales information on the forms provided by the Lottery. The information required includes the number of cash registers, hours of operation, products presently offered for sale, and the approximate daily volume of customers entering the place of business;
 - e. Evidence the applicant operates a business with other products or services unrelated to lottery products or services concerning lotteries;
 - f. Financial relationship and any outstanding debt owed to the state of Arizona, any of its political subdivisions, or the United States government;
 - g. Evidence the applicant for a full product license is financially solvent. The evidence may include either of the following:
 - i. Evidence the applicant has established business credit, has a record of meeting its business debts as they became due for the three years immediately preceding the date of application, and does not have outstanding legal actions, judgments, or tax liens; or
 - ii. Personal guarantee, in writing, of applicant's Lottery account signed by a guarantor and the guarantor's spouse, if community property is being used to guarantee the account, or by the guarantor only, if guarantor provides proof that the guarantee is based on sole and separate property.
 - h. An Electronic Funds Transfer Authorization agreement showing a valid bank account number for the full product applicant from which the Lottery will withdraw any amounts due.
2. If the applicant does business as a sole proprietorship or partnership:
 - a. The name, home address, and home phone number of each owner or partner, including spouse if community property owner, unless applicant provides proof that the business is sole property separate from the community; and
 - b. Written authorization and tax identification number for the business entity and Social Security number of each applicant in order to obtain a credit check from a credit reporting agency; ~~and~~.

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- e. ~~A completed, authorized fingerprint card for the applicant. If any general partner is a corporation, a fingerprint card is required under subsection (4).~~
- 3. If the applicant does business as a limited liability partnership ("LLP") or a limited liability company ("LLC"):
 - a. The name, home address, and home phone number of each partner or member; and
 - b. Written authorization and a tax identification number to perform a credit check; and.
 - e. ~~A completed authorized fingerprint card for each partner or member.~~
- 4. If the applicant does business as a corporation:
 - a. The name, corporate address, and corporate phone number of each officer and director, and the name, home address and home phone number of the responsible local premise manager who is the contact representative for the applicant's corporate location in Arizona; and
 - b. Written authorization and a tax identification number to perform a credit check; and.
 - e. ~~A completed authorized fingerprint card for the appropriate responsible local premise manager.~~
- 5. If the applicant does business as a charitable organization:
 - a. A copy of the organization charter or formation, documentation of current membership status in the organization, and if applicable, the authorization of the auxiliary;
 - b. The name, home address, and home phone number of each officer and local premise manager, or if an auxiliary, of each officer and local premise manager of the auxiliary;
 - c. A letter of determination issued in the organization's name by the United States Internal Revenue Service verifying the organization's tax-exempt status; and
 - d. ~~A completed authorized fingerprint card for each officer and local premise manager, or if an auxiliary, of each officer and local premise manager of the auxiliary; and~~
 - e. d. Evidence the charitable organization has maintained a premise within the state of Arizona for the two years immediately preceding the date of application.
- 6. If the Lottery licenses an applicant under subsection (1)(g)(ii), the guarantor shall provide a written authorization to perform a credit check. If the guarantee is based on community property, the guarantor and guarantor's spouse shall provide written authorization for the Lottery to perform a credit check.
- 7. An application fee of \$45.00 and ~~the following fees, if applicable:~~ an additional credit check fee of \$22 if the applicant does business as a corporation, limited liability company, limited liability partnership, or partnership.
 - a. ~~If any individual listed on the personal questionnaire has resided outside the state of Arizona within the last 10 years, a fingerprint fee per individual as set by the Department of Public Safety.~~
 - b. ~~If the applicant does business as a corporation, limited liability company, limited liability partnership, or a partnership, a credit check fee of \$22.~~
- 8. If the applicant is a business with more than one currently licensed location, the application fee for the new location shall be pro-rated at \$1.25 per month from the application date until the date the other licenses are due for renewal under R19-3-202.04(B)(3).